

DIVISION OF RESEARCH AND INNOVATION

Joint Research and Development Office / Clinical Research Facility

Document Number: GOSH/ICH/SOP/CRF/002	Version Number: 05
Title: Booking Appointments, Admission, Discharge and Transfer of Study Participants in the CRF	
Effective Date:	19-Jul-21

	Name	Position
Authored by:	Moonsang Seo	CRF Service Manager
Approved by:	Grant Nicholson	Head of Clinical Research Operations

1. Scope

This Standard Operating Procedure (SOP) is applicable to all staff involved in arranging appointments in or supported by the CRF (including protocol required telephone and video appointments), admitting and discharging participants to/from the CRF, and transferring participants from the CRF to other GOSH wards/departments.

2. Purpose

The purpose of this SOP is to outline the procedure for booking study appointments in or supported by the CRF (including protocol required telephone appointments), for admitting and discharging participants to/from the CRF and for transferring participants from the CRF to other GOSH wards/departments.

3. Definitions/Abbreviations

Epic – Trust Electronic Patient Record System

DO NOT MAKE UNAUTHORISED COPIES

This is a controlled document. Any print-offs or downloads of this document will be classed as uncontrolled and colleagues are advised to refer to Q-pulse for the latest version.

4. Responsibilities

Duties may be delegated but the responsibility always remains with those listed.

4.1 Research Team are responsible for:

- Ensuring participant visits (including protocol required telephone appointments) are booked with the CRF in advance and that the CRF Reception Team are notified of any changes to the booking.
- Arranging the participant visit (and any confirmations/alterations) with the participant (if age appropriate) and/or family.
- Raising an Order on Epic – *CRF Appointment Request* and associating with a study record
- Ensuring the CRF Reception Team are aware if the visit has been attended or cancelled (particularly if telephone/video appointment, lab only visit or visit outside CRF)

4.2 CRF Reception Team is responsible for:

- Booking participant visits on Epic.
- Check in / Admitting participants on epic between the hours of 08:00-17:00
- CRF Reception Team should contact CRF Service Manager if they are asked to book a visit for a study that has not been appropriately raised as an order on epic.
- Marking on CRFManager® once a participant 'Attended' or 'Cancelled' and accurately recording the actual check in and check out time

4.3 Research Nurse is responsible for:

- Ensuring the room allocated is suitable for the study visit.
- Participants must be discharged on Epic immediately after the visit has been completed.
- Informing CRF Reception Team that a participant has left (08:00-17:00).
- Admitting and discharging participants on Epic outside the hours of 08:00-17:00.
- Recording on Epic the transfer of a participant in the event that the participant is transferred for a scheduled overnight stay, for specialist care following a serious adverse event or in situations where occupancy of the CRF is denied.

4.4 CRF Service Manager is responsible for:

- All staff have appropriate access to Epic and CRFManager®
- Reporting CRF activities

4.5 All staff involved with the booking, admission, transfer and discharge of participants in the CRF are responsible for:

- Ensuring their practice meets the requirements of this SOP and the relevant Trust policies and guidelines (particularly Trust Information Governance Policy, Patient Identification policy, and Patient Transfer Policy).

DO NOT MAKE UNAUTHORISED COPIES

This is a controlled document. Any print-offs or downloads of this document will be classed as uncontrolled and colleagues are advised to refer to Q-pulse for the latest version.

5. Procedure

5.1 Booking a visit

CRF clinical space, Clinical Research Lab resource or monitoring space must be booked in advance. Protocol required telephone appointments supported by the CRF must also be booked on Epic for reporting purposes.

To book CRF clinical space, protocol required telephone appointments or monitoring space; the Research Team (usually the Research Nurse or Research Coordinator) must raise an order in Epic for CRF Appointment Request

To book only Clinical Research Lab resource the Research Team must complete CRF Booking Request Form and submit to CRF.Bookings@gosh.nhs.uk with as much notice as possible.

If there are changes or cancellations to a booking, the Research Team must let the CRF Reception Team know as soon as possible. Research Team should not change any appointments on Epic without informing the CRF Reception Team.

The appointment(s) (and any alterations) and the actual check in and discharge time of participants will subsequently be entered into the 'CRFManager®' by the CRF Reception Team for reporting purposes.

If CRF clinical space is requested, the participant will be allocated to a specific CRF clinical investigation room. It is the responsibility of the Research Nurse to ensure the room allocated is appropriate for the study visit.

5.2 Preparation for a visit

The participant (as age appropriate) and/or family can be contacted by the Research Team in the days prior to the appointment, to remind them of the date/time and help to reduce the risk of non-attendance.

5.3 Admitting a participant to the CRF

All participants that attend an appointment in the CRF must have the visit scheduled on Epic which has been ordered in advance by the research team and booked by reception team.

Upon arrival the CRF Reception Team (or delegate) will welcome the participant and their family and direct them to the seating area and/or investigation room and offer complementary refreshments as appropriate. The CRF Reception Team (or delegate) will inform the relevant study team members of the participant's arrival.

DO NOT MAKE UNAUTHORISED COPIES

This is a controlled document. Any print-offs or downloads of this document will be classed as uncontrolled and colleagues are advised to refer to Q-pulse for the latest version.

CRF Reception Team (or delegate) must confirm participants name, address, contact details, next of kin and GP details on arrival, to ensure the information held on Epic is accurate and current. If amendments are required, these must be made as soon as possible.

The CRF Reception Team (08:00 – 17:00) or Research Nurse (outside 08:00 - 17:00) must record the participant's admission on Epic and ensure the visit is linked to their study record on Epic. This must be done within one hour of the participant's arrival.

The Research Nurse must update appropriate clinical documentations on Epic as required during their study visit. This is essential for participant safety.

5.4 Discharging a participant from the CRF

On completion of the participant's visit to the CRF; the Research Nurse or other clinical team involved in the visit must discharge the participant on Epic.

5.5 Non-attenders

If the participant does not attend their appointment it must be entered as a DNA (Did Not Attend) on Epic.

5.6 Transferring participants from the CRF to other Trust wards/departments

When a participant admitted to the CRF is transferred from the CRF to another GOSH ward/department for a scheduled overnight stay, for specialist care following a serious adverse event or in situations where occupancy of the CRF is denied, the Research Nurse caring for the participant will record the transfer on Epic. Participants admitted to the CRF who visit other GOSH departments for investigations and/or tests that are scheduled as part of the study visit and who are scheduled to return to the CRF following the investigation/test will not be recorded on Epic as being transferred unless advised by the study team.

6. Related Documents

- GOSH/ICH/FRM/CRF/003 CRF Booking Request Form
- Trust Information Governance Policy
- Patient Identification Policy
- Patient Transfer Policy
- Trust Epic Downtime Procedures

7. References

None

DO NOT MAKE UNAUTHORISED COPIES

This is a controlled document. Any print-offs or downloads of this document will be classed as uncontrolled and colleagues are advised to refer to Q-pulse for the latest version.